



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :  
Walter ELGER et al. : Group Art Unit: 1617  
Serial No.: 09/744,574 : Examiner: JIANG, Shaojia A.  
Filed: 5 April 2001 :  
For: USE OF BIOGENIC ESTROGEN SULFAMATES FOR HORMONE REPLACEMENT  
THERAPY

**REPLY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SIR:

In response to the Office Action mailed on October 4, 2004, please consider the following remarks.

The only outstanding rejection is an obviousness-type double patenting rejection over US 6,653,298, where the Office Action alleges that the patent is deemed to encompass the instant claims.

However, the test for obviousness-type double patenting is not whether the patent over which the claims are rejected encompasses the claims. Rather, the test encompasses a two step inquiry, i.e., the first question in the analysis is: "Is the same invention being claimed twice?" and if the answer to this first question is no, which is admitted in the Office Action, then the second analysis question is: "Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent?" See *In re Vogel*, 422 F.2d 438, 164 USPQ 617 (CCPA 1970).

The answer to the second question has already been answered in the negative in this case on appeal over two references (WO 96/05216 and US 5,314,694), which posed the question of whether a teaching of daily administrations renders the current claims obvious. The Board held that a teaching of daily administration did not render obvious the intermittent administration of the present claims. See the Board decision in this case mailed on March 25, 2004.

The claims of US 6,653,298 are directed to administrations of "no greater than 200  $\mu\text{g/day}$  per 70 kg subject" (see independent claims 1-3) and "from 10 to 200  $\mu\text{g/day}$ " (see